

REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 1, 7, 11, 12, 18 and 19 have been amended herein. Claims 3, 4, 6, 9 and 10 have been cancelled herein. Care has been exercised to introduce no new matter. Accordingly, claims 1, 2, 5, 7-8, and 11-21 are pending and are in condition for allowance.

Rejections based on 35 U.S.C. § 102(b)

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 19133, 1920 (Fed. Cir. 1989); *see also*, MPEP § 2131.

Claim 11 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Wagner (U.S. Patent No. 6,092,102, hereinafter “the Wagner reference”). As the Wagner reference does not describe, either expressly or inherently, each and every element of the rejected claim, applicants respectfully traverse the rejection as hereinafter set forth.

Independent claim 11, as amended herein, is directed to a method in a computing environment for communicating a laboratory result to a person placing a laboratory order. The method includes accessing a data store containing a plurality of clinical laboratory results, accessing an electronic medical record data store containing clinical event information, selectively identifying a clinical laboratory result requiring communication to the person placing the laboratory order for the selected clinical laboratory result based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order, identifying a first preferred notation method for the selected laboratory

result and automatically generating a communication of the selected laboratory result by the first preferred method.

By way of contrast, the Wagner reference describes a system and method for notifying users about information or events of an enterprise by incorporating user preferences for communication channels to communicate a message as a function of the message, such as based on the message type. *See Wagner* at col. 3, lines 31-34. It is respectfully submitted that the Wagner reference fails to describe accessing an electronic medical record data store containing clinical event information, as described in the invention of claim 11. Instead the Wagner reference discloses “a data reception sub-system [that] receives information from a data generation sub-system such as a laboratory information system.” *Id.* at col. 7, lines 22-24. The existence of the words “data reception sub-system” does not teach Applicants’ claimed invention. MPEP § 2131 states that a “claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131 also states that the identical invention must be shown is as complete detail as contained in the claim. Applicants respectfully submit that accessing an electronic medical record data store is absent from Wagner. As shown by the Office’s reasons for the rejection of claim 1, “Wagner does not disclose an electrical medical record data store.” *See Office Action*, page 2. The Wagner reference fails to teach or suggest accessing an electronic medical record data store containing clinical event information. Thus, the system and method of the Wagner reference lacks the ability to suggest a method for communicating laboratory results to a person placing a laboratory order in the same manner that could be achieved in the invention recited in amended claim 11.

Accordingly it is respectfully submitted that the Wagner reference fails to describe, either expressly or inherently, each and every element of independent claim 11.

Moreover, the Wagner reference fails to show the identical invention in as complete detail as contained in the claim. Thus, it is respectfully submitted that claim 11, as amended herein, is not anticipated by the Wagner reference. Therefore withdrawal of the 35 U.S.C. § 102(b) rejection of claim 11 is respectfully requested.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestion or motivation found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, *Application of Bergel*, 292 F. 2d 955, 956-957 (1961). Thus, in order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must

teach or suggest all the claim limitations.” See MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application].” *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Wagner reference in view of U.S. Patent Application Pub. No. 2004/0034550 to Menschik et al., (hereinafter, “the Menschik reference”). As the asserted combination of references fails to teach or suggest each and every of the limitations set forth in the rejected claims, Applicants respectfully traverse these rejections, as hereinafter set forth.

Independent claim 1, as amended herein, is generally directed to a computerized system for managing the communication of a laboratory result to a person placing a laboratory order. The system comprises a laboratory information system data store storing clinical laboratory results for clinical laboratory orders, an electronic medical record data store storing clinical event information, and a results posting module communicating with the laboratory information system data store and electronic medical record data store. The results posting module is configured to publish clinical laboratory results from the laboratory information system data store to the electronic medical data store. Also, the results posting module publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. The system also includes a callback module for selectively identifying a clinical laboratory result requiring a communication to the person placing the laboratory order for the selected clinical laboratory result. The callback module selectively

identifies the clinical laboratory result requiring communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order.

Amended independent claim 7 recites a method in a computer environment of managing the communication of a laboratory result to a person placing a laboratory order comprising accessing a laboratory information system data store containing a plurality of laboratory results, posting the laboratory results from the laboratory information system data store to an electronic medical records data store, analyzing the clinical laboratory order for the clinical laboratory results, comparing the laboratory result to a clinical range relevant to the laboratory result, and selectively identifying a clinical laboratory result requiring a communication to the person placing the laboratory order.

Applicants respectfully submit that none of the references, taken singularly or in combination, teach or suggest the combination of a system for managing the communication of a laboratory results to a person placing a laboratory order. In particular, the collective disclosure of the references fail to teach or suggest a results posting module that publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. The collective disclosure of the reference also fails to teach or suggest a callback module that selectively identifies the clinical laboratory result requiring communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order.

In contrast to the inventions of claims 1 and 7, the Wagner reference discloses a system and method for notifying users about information or events of an enterprise by incorporating user preferences for communication channels to communicate a message as a

function of the message, such as based on the message type. *See generally, Wagner* at col. 3, lines 31-34.

As indicated in the Office action, the Wagner reference fails to teach or suggest a results posting module that publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. In the Wagner reference “a data reception sub-system receives information from a data generation sub-system such as a laboratory information system or radiology information system.” *Id.* at col. 7, lines 22-24. In contrast, Applicants’ claimed invention teaches posting laboratory results from the laboratory information system into an electronic medical records database that stores clinical event information. *See Specification*, ¶ [0022]. As defined in the Specification, a clinical event includes but is not limited to, documentation of patient activities, patient history, discharge summaries, medication administration records, and test results. *Id.* at ¶ [0022]. Applicants respectfully submit that the Wagner reference fails to disclose posting clinical laboratory results directly to an electronic medical records data store.

The Wagner reference also fails to teach or suggest a callback module that selectively identifies the clinical laboratory result requiring communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order as disclosed in the claimed invention. MPEP 2111 states that “claims must be given their broadest reasonable interpretation consistent with the specification.” MPEP 211.01 also states “words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification.” The specification at paragraph [0023] discloses that the callback module “evaluates the laboratory results using callback criteria . . . based on the ordered procedure, resulted assay, reference range flag, critical range flag, ordering physician or ordering location.” *See Specification* at [0023]. The Wagner

reference describes a event monitor that “employs the stored information for determining an event and generating a responsive message” *See Wagner, Abstract*. Wagner discloses “matching the contents of the working memory (e.g. patient data and information about drugs coming out of the database) against the condition of a production, and then executing the action.” *Id.* at col. 8, lines 31-34. However, the Wagner reference is silent on comparing the laboratory result to a clinical range relevant to the laboratory result, utilizing information about the clinical laboratory order and other callback criteria to determine if a callback is appropriate, as described in the inventions of claims 1 and 7. Applicants respectfully submit that to equate the event monitor disclosure of Wagner to “identifying the clinical laboratory result requiring communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order” would be beyond the broadest reasonable interpretation consistent with Applicants’ specification.

The Office has acknowledged that the Wagner reference fails to teach the computer implemented aspects the inventions of claims 1 and 7 including the aspect of an electronic medical records data store. *See Office Action* at p. 2. The Office asserts that the Menschik reference teaches the above-mentioned feature. By the combination of these two references, the Examiner argues that it would have been “obvious . . . to combine the teachings of Wagner with those of Menschik in order to facilitate medical data transfer among systems.” *See Office Action* at p. 3.

The Menschik reference is directed to a method for creating a secure, centrally-mediated, peer-to-peer network of healthcare providers requiring no pre-existing affiliations of each other. *See Menschik* at ¶ [0027]. Menschik discloses a electronic medical record system that permits healthcare providers to enter clinical observations and retrieve patient notes and charts, while a clinical data repository provides storage for patient records. *Id.* at ¶ [0092].

With continued reference to claims 1 and 7, Applicants respectfully submit that the Menschik reference does not describe a results posting module that publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. Instead the Menschik reference discloses a system with “a series of software programs indicated as ‘brokers’ for communicating with various hospital facilities.” *Id.* at ¶ [0094]. When evaluating the scope of a claim, every feature in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. *See* MPEP §2106. The absence of a description in Menschik for posting laboratory results *directly* from the laboratory information system data store to the electronic medical records data store prevents Menschik from disclosing a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claim 1.

As the Wagner reference in view of the Menschik reference fails to teach or suggest all the limitations of the independent claim 1, a *prima facie* case of obviousness has not been made for independent claims 1 and 7 with respect to these references. Accordingly, Applicants respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection of these claims.

Claims 2-6, and 8-10 depend respectively from independent claims 1 and 7. As such, Applicants respectfully submit that claims 2-10 are patentable over the Wagner and Menschik reference for at least the above reasons.

Claims 12-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Wagner reference. As the asserted reference fails to teach or suggest all of the limitations set forth in the rejected claims, Applicants respectfully traverse these rejections, as hereinafter set forth.

Dependent claims 12-17 depend from independent claim 11. As set forth above, independent claim 11 is allowable over the Wagner reference, and claims 12-17 are thus allowable for at least the reasons set forth above. Dependent claim 12 has been amended herein to address examiners concern that claim 12 recites an optional step. *See Office Action*, pg. 4.

As amended, independent claim 18 is directed to a method in a computing environment for communicating a laboratory result to a person placing a laboratory order comprising accessing a data store containing a plurality of clinical laboratory results, accessing an electronic medical record data store containing clinical event information; selectively identifying a clinical laboratory result requiring communication to the person placing the laboratory order for the selected clinical laboratory result based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order; identifying a first preferred notification method for the selected laboratory result from a plurality of notification methods; identifying a number of conditions for the preferred method; and if the conditions are satisfied, automatically generating a communication of the laboratory result by the first preferred method.

The Wagner reference does not teach or suggest determining if the communication of the laboratory result is not completed, wherein a second preferred method for the selected laboratory result is identified and wherein a communication of the laboratory result by the second preferred method is generated. Instead the Wagner reference discloses a system where “if acknowledgement is not provided by the user within a preferred time, then the message is resent to the user and the process of checking for the acknowledgement is repeated. *See Wagner* at col. 14, lines 42-46. Wagner discloses using a single method to send a notification to a user and reusing the method to resend the notification in instances where delivering an initial notification to the user failed. Wagner does not disclose identifying a second preferred method

for the selected laboratory result, and generating a communication of the result by the second preferred method as described in the claimed invention. Instead Wagner merely discloses resending the message via the same method used in the initial attempt. *Id.*

Moreover, official notice without documentary evidence is permissible only in some circumstances to support an examiner's conclusion. See MPEP § 2144.03 (A). "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known." *Id.* (emphasis in original). "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." MPEP § 2144.03(C).

The Office Action took official notice without providing supporting documentation, stating "a predictable result" of Wagner's invention "would be to resend the message using one of the disclosed several other communication channels." See *Office Action* at p. 4. While a clinician may prefer notification using communication channels such as emails or paging systems, it is not common knowledge for a clinician to request initial notification by a preferred channel and an alternative communication channel in the event the first notification is unsuccessful.

Therefore, the Wagner reference fails to teach or suggest all of the features of dependent claims 12, and 19. Accordingly, these claims are believed to be in condition for allowance, and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection thereto.

Regarding independent claims 11 and 18, Applicants respectfully submit that the Wagner reference does not teach or suggest the combination of a system for managing the

communication of a laboratory results to a person placing a laboratory order. In particular the collective disclosure of the reference fails to teach or suggest a results posting module that publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. The collective disclosure of the reference also fails to teach or suggest a callback module that selectively identifies the clinical laboratory result requiring communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order. The same reasons traversing the rejections provided above for claims 1 and 7 are applicable here. When evaluating the scope of a claim, every feature in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. *See* MPEP §2106 II C. As dependent claims 13-17 and 20-21 depend from claims 11 and 18, when dependent claims 13-17 and 20-21 are considered as a whole in accordance with §2106 II C, the same reasons traversing the rejections provided for claims 11 and 18 are applicable here. Accordingly, Applicants respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection of these claims.

Dependent claim 19 has been amended herein to address examiners concern that claim 19 recites an optional step. *See Office Action*, pg. 4.

CONCLUSION

For at least the reasons stated above, claims 1, 2, 5, 7-8, and 11-21 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or ddevers@shb.com (such communication via email is herein expressly granted) – to resolve the same.

REQUEST FOR EXTENSION OF TIME

It is hereby requested that the time period for responding to the outstanding Office Action mailed August 11, 2008, be extended for three months or until February 11, 2009. The Petition fee of \$1,110.00 is being submitted simultaneously with this paper by way of electronic payment.

In the event it is determined necessary, the Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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